

SF-36 questionnaire was administered to patients who received COS with follitropin alfa ($n = 22$) or follitropin beta ($n = 21$) in a randomized controlled clinical study. SF-36 scores before and after COS were obtained for each patient. Results for the eight “dimensions” of the SF-36 were projected using multifactorial analysis to produce a composite QOL score. Statistical tests were performed to determine the percentage of relevant information captured by the multifactorial analysis and hence the quality of the composite score. The bootstrap technique was used to generate additional random samples. The Kolmogorov–Smirnov test was used to compare the distributions of the composite scores for the follitropin alfa and beta groups. **RESULTS:** The test performed to validate the composite QOL score gave a value of 0.55 (55% of relevant information captured), compared with an expected score of 0.125 for a random projection of eight dimensions into one. The distribution of composite scores for the two groups was significantly different after 30 simulations ($p = 0.004$), suggesting a difference in the effects of the two treatments on QOL. A graphical plot of the results of 5000 simulations showed that the follitropin beta group had a greater reduction in QOL as a result of COS compared with the follitropin alfa group. **CONCLUSIONS:** Mathematical modeling confirms a statistically significant difference in QOL effects of the two r-hFSH preparations in favor of follitropin alfa.

PWH6**PATIENT AND PARTNER TREATMENT SATISFACTION SCALE (TSS) IN ERECTILE DYSFUNCTION**

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OBJECTIVE: To develop an instrument to assess male patient's and their female partner's satisfaction with the treatment for erectile dysfunction (ED) and assess the comprehensiveness, comprehension, acceptability and clarity of the instrument. **METHODS:** Four phases were performed in the questionnaire development; item generation, face and content validity, cognitive debriefing, cultural and language adaptation. Item generation was based on literature review, hypothesized characteristics of the drug and in-depth interviews with patients and their partners. Perceptions and feelings related to the condition and their expectations of treatment were examined. Items were generated simultaneously in English, French, and German and adapted to each culture. Content and face validity were assessed by interviews with patients and partners in 5 countries. Testing of structure and response scales, cognitive debriefing and verification of conceptual equivalence between languages was assessed. **RESULTS:** A total of 55 interviews were conducted to test face and content validity for patients, partners and experts. The

final content areas deemed important included spontaneity, quality of erection, quality of ejaculation, sexual pleasure, satisfaction with orgasm, confidence, reliability of treatment, side effect, convenience, overall satisfaction, conformity to treatment expectations and intentions for continued use of drug. Cognitive debriefing with patients and partners found no problems with comprehension. Results of the debriefing found some words to be problematic. There were no cultural differences found between the English, French, or German version. The questionnaire was revised at each phase. The final questionnaire for both the patient and the partner contained 19 questions. The questionnaire was then translated into 14 additional languages for use in clinical trials. **CONCLUSIONS:** The TSS is a comprehensive measure of male ED patients and their respective partners. Further work is needed to validate the TSS, identify the domains, test the responsiveness and determine the appropriate scoring.

PWH7**A NEW INSTRUMENT TO MEASURE THE PSYCHOLOGICAL IMPACT OF ERECTILE DYSFUNCTION. VALIDATION OF A SPANISH VERSION OF THE JOHNSON AND MCCOY'S SELF-CONFIDENCE SCALE**

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Erectile dysfunction has an impact on Health Related Quality of Life. It can be expected that it also has some impact on psychological well-being-related variables, such as self-confidence and self-esteem. It is, therefore, worthwhile making available in different languages validated versions of instruments able to measure these parameters. **OBJECTIVE:** To perform the linguistic and psychometric validation of a cultural adaptation to Spanish of the Johnson and McCoy's Self-Confidence Scale to be used in patients with erectile dysfunction (ED). **METHODS:** After conducting a linguistic validation of the scale through two forward translations, backward translation, and cognitive debriefing interviews the final reconciled version of the scale was to be administered to 200 male patients with ED and 200 male subjects without ED. Participants were screened for ED by general practitioners and further reviewed by urologists. In addition to the self-confidence scale, all participants were asked to answer the Rosenberg's self-esteem scale. **RESULTS:** A total of 387 subjects completed the self-confidence questionnaire. It showed a high internal consistency (Cronbach's alpha = 0.82), similar to the original English version (Cronbach's alpha = 0.84). All items showed a high correlation with the scale. The correlation of the scale with self-esteem score was adequate ($r = 0.60$). A factorial structure of 5 dimensions was observed in the Spanish version of the self-confidence scale comparable to the original structure. Self-confidence scores were